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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,072

Applicant(s)

G. ET AL.

Examiner

Kathleen Sonnett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/14/2006 have been fully considered but they are not persuasive.
2. Regarding the rejection of claims 1-3, 9 and 12 under 35 USC 102(b) as being anticipated by Nicholas (5,431,662), Applicant argues that element (240) is not a vaginal delineator, but rather a seal. However, no significant structure is given to the vaginal delineator in either claims 1 or amended claim 2 to exclude a seal that is attached to the shaft of the uterine manipulating device. Furthermore, the seal is capable of manipulating the uterus since it engages the walls of the uterus. It is the examiner's position that the seal (240) disclosed by Nicholas can be used to manipulate the vagina and therefore, Nicholas anticipates claim 1.
3. Regarding amended claims 2, 9, and 12, the vaginal delineator of Nicholas is being considered a uni-body construction as it does not contain any readily detachable parts.
4. Regarding the rejection of claims 1-3, 7-9, 12, and 16-18, under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. (U.S. 5,643,285) in view of Nicholas (U.S. 5,431,662). Applicant argues that it would not be obvious to modify Rowden to include a curved shaft on the uterine manipulating device. However, Rowden does not teach away from the addition of a curved shaft as no indication of disadvantages associated with a curved shaft is given in the patent. Furthermore, Nicholas et al. discloses the advantages of having such a curved shaft including ease of insertion. Applicant further argues that the vaginal delineator of Rowden will not seal the vaginal cavity due to the presence of windows. However, no such structural limitation regarding the formation of a seal is given in any of the above claims.

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5. Regarding applicant's arguments for claims 7, 8, 16, and 17, the examiner maintains her position that an outer diameter of 1.5 or 1.6 inches is obvious in light of Rowden et al.'s disclosure of an outer diameter of 1.436 inches since no criticality to this value is given in the specification of the instant patent application in regards to any advantage of using this dimension or disadvantage of using a dimension other than 1.5 or 1.6 inches. Furthermore, the modification of adding a curved shaft to the device of Rowden et al. would not seem to impact the choice of diameter of the device.

6. Regarding applicant's arguments for claims 4, 10, 11, 13, and 19, the modified device of Rowden et al. discloses the invention of independent claims 1, 2, and 9 from which claims 4, 10, 11, 13, and 19 depend. The addition of a handle with a diameter of 2.54 cm and a radius of curvature of 6 inches for the device are obvious in view of Harris and Fox since these values are employed in devices inserted into the vaginal canal. Furthermore, no criticality is given in the instant specification for these particular values and no drawbacks are given for measurements that would fall out of this range.

7. For the above reasons, the rejections previously presented in the Office Action dated 4/17/2006 have been maintained. Rejections for newly added claims 20-23 have been added.

8. Applicant's amendment has overcome the objections to the specification and claim 12 previously presented in the Office Action dated 4/17/2006

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. **New claims 20 and 22** are rejected under 35 U.S.C. 102(b) as being anticipated by Van Maren (U.S. 3,926,129). Van Maren discloses a uterine manipulating device comprising a curved shaft (14), an enlarged portion (16) of slightly larger diameter than the shaft that can be used as a handle, a uterine tip end (44) of slightly smaller diameter than the shaft, a vaginal delineator (24), and a means for attaching the vaginal delineator to the shaft (20) (Fig.1-5). Uterine tip end (44) has a diameter that becomes smaller than the diameter of the shaft as you near the distal end of the uterine tip (see fig. 5). The vaginal delineator (24) is of a uni-body construction and in the general shape of a cup, the lip of which seals the vaginal cavity from the uterus. In particular, the shaft is hooked up to a vacuum source, which causes the uterine wall surrounding the cervical os to be pulled against the lip (36) of the delineator and into space (38) (col. 2 lines 27-34). The vaginal cavity is then sealed from the uterus.

11. **Claims 1, 2, 3, 9 and 12** are rejected under 35 U.S.C. 102(b) as being anticipated by Nicholas (U.S. 5,431,662). Nicholas discloses a uterine manipulating device comprising a curved shaft (214) with a radius of curvature of 8 inches, a handle end (212) of slightly larger diameter than the shaft, a uterine tip end (221) of slightly smaller diameter than the shaft, a vaginal delineator (240), and a means for attaching the vaginal delineator to the shaft (274) (Fig. 13, 18, and col. 8 lines 43-62, col. 10 lines 1-21). Uterine tip end (221) is of a uni-body construction and is a crowned atraumatic tip and as seen in Fig. 18, as you near the distal end of the uterine tip, the diameter becomes smaller than the diameter of the shaft.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **New claims 20-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagel (2,400,251) in view of Nicholas (U.S. 5,431,662). Nagel discloses a uterine manipulating device comprising a curved shaft (104), a handle end of slightly larger diameter than the shaft (48 which 106 fits into; see col. 4 lines 1-4), a uterine tip end (80) of slightly smaller diameter than the shaft, a vaginal delineator (84), and a means for attaching the vaginal delineator to the shaft (90, 92) (Fig. 1, 3, 11, and 12). The vaginal delineator (84) is of a uni-body construction and in the general shape of a cup, the lip of which seals the vaginal cavity from the uterus. In particular, the uterine wall surrounding the cervical os is pushed against the lip of the delineator and into space (20) (see Fig. 1). The vaginal cavity is then sealed from the uterus (see also elements 90 and 92). Although the uterine tip end has holes, the tip is placed in the uterus and the lumen that the holes open into does not have another opening until you reach a portion of the shaft that is outside of the patient. The lip of the device delineates the surgical incision to be made between the uterus and the cervix (col. 3, lines 15-27). Nagel fails to disclose a shaft that is curved in the shape of a female cervix.

14. However, Nicholas discloses that it is old and well known in the art to curve a shaft on a uterine manipulating device to include a curve that mimics the shape of female cervix (col. 8 lines 43-61). This shape facilitates insertion of the device into a patient. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Van Maren to curve the shaft in the shape of the female cervix as made obvious by Nicholas in order to facilitate insertion of the device.

15. **Claims 1-3, 7-9, 12, and 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. (U.S. 5,643,285) in view of Nicholas (U.S. 5,431,662). Rowden et al. discloses a uterine manipulating device comprising a shaft (16), having a handle end (28) of a slightly larger diameter than the shaft, a uterine tip (64) of slightly smaller diameter than the shaft, a vaginal delineator (20) made of a uni-body construction and means for attaching the vaginal delineator to the shaft (col. 4 lines 47-59). Rowden et al. fails to disclose that the shaft has a curved shape of a female cervix.

16. However, Nicholas discloses that it is old and well known in the art to shape uterine manipulating devices in a general curved shape of a female cervix. Nicholas further discloses a radius of curvature of the shaft to be 8 inches (col. 8 lines 43-61). This shape facilitates insertion of the device into a patient. Nicholas also discloses that it is old and well known in the art to include a handle and shaft that are threaded so as to be removably attached to each other ([0093]). A manipulator with a removable handle gives the advantage of being easy to sterilize. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Rowden et al. to include a curved shaft and handle and shaft that are removably attached as made obvious by Nicholas in order to gain the advantage of easy insertion and easy sterilization of the device.

17. Regarding claims 7, 8, 16, and 17, Rowden et al. discloses an outer diameter for the vaginal delineator as 1.436 inches (col. 5 lines 1-6). Therefore, a diameter of 1.5 with regards to claims 7 and 16, and a diameter of 1.6 inches with regards to claims 8 and 17 is considered obvious since no criticality is given in the specification of the instant patent application for a diameter of 1.436 inches. Also, it is the examiner's position that a device that is 0.164 inches smaller than 1.6 inches will perform as well as a delineator with a diameter of 1.6 inches.

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18. **Claims 10 and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. and Nicholas et al. as applied to claim 1 above and in further view of Harris (U.S. 4,430,076). The modified device of Rowden et al. discloses the invention substantially as stated above but fails to disclose a diameter of 2.54 cm for the handle.

However, Harris discloses that it is old and well known in the art to size a handle for a uterine manipulating device to be *about* 2 cm. There is no criticality given in the specification for a diameter of between 2.03 and 3.8 cm or a diameter of 2.54 cm for the handle. It is the examiner's position that a device with a handle having a diameter that is 0.54 cm less than the claimed 2.54 cm value will perform equally as well. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include a handle which measures 2.54 cm because Harris discloses that *about* 2 cm is an effective diameter for a handle on a uterine manipulating device.

19. **Claims 4 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. in view of Nicholas as applied to claim 1 above and in further view of Fox et al. (U.S. 5,437,628). The modified device of Rowden et al. discloses the invention substantially as stated above but fails to disclose that the radius of curvature is 6 inches.

20. However, Fox et al. discloses that it is old and well known to give a radius of curvature of 6 inches to a device that will be inserted into the vaginal canal in order to facilitate an easy insertion (col. 3 lines 27-40). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include a shaft with a radius of curvature of 6 inches made obvious by Fox et al. in order to follow the path of the vaginal canal and cervix for easy insertion.

21. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. in view of Nicholas et al. as applied to claim 1 above and in further view of Hasson (U.S.

5,562,680). The modified device of Rowden et al. discloses the invention substantially as stated above, but fails to disclose that the uterine tip and the end of the shaft opposite to the handle are threaded so as to be removably attached to each other.

22. However, Hasson discloses that it is old and well known in the art to include a uterine tip and shaft that are threaded so as to be removably attached to each other (Fig. 8, col. 4 lines 30-33). This allows for the interchange of different uterine tips. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include a uterine tip and shaft that are threaded so as to be removably attached to each other as made obvious by Hasson in order to be able to interchange uterine tips and for ease of cleaning.

23. **Claims 5, 6, 14, and 15** rejected under 35 U.S.C. 103(a) as being unpatentable over Rowden et al. and Nicholas as applied to claim 1 above, and further in view of Singh et al. (U.S. 6,423,075) and Smith et al. (U.S. 5,645,561). The modified device of Rowden et al. discloses the invention substantially as stated above, but fails to disclose values for the diameter of the shaft, the diameter of the uterine tip end, or the length defined by the distance between the end of the uterine tip and the vaginal delineator.

24. However, Smith et al. discloses a uterine manipulator with a uterine tip (54) that has a diameter of *about* 0.2 inches (col. 8 lines 4-7 and Fig. 2). Smith et al. further discloses that the distance between the uterine tip and the vaginal delineator is from about 6 cm to about 8 cm. Although the diameter of *about* 0.2 inches for the uterine tip does not fall within the broad range of 0.25 to 0.45 inches and further does not match the value given in claim 6 and 15 of 0.375 inches, it is the examiner's position that a device with a uterine tip having a diameter of about 0.2 inches will perform equally as well as a device with a uterine tip having a diameter of 0.375 inches. Additionally, no criticality is given in the specification for the specific diameter value. Regarding the diameter of the shaft, Singh et al. discloses that it is old and well known in the art

to include on a uterine manipulating device a shaft with a diameter between 10 mm and 30 mm. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Rowden et al. to include the dimensions made obvious by Smith et al. and Singh et al. because the dimensions are given as effective dimensions for uterine manipulating devices and no criticality is given in the specification for the particular values of the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
8/18/2006


GLENN K. DAWSON
PRIMARY EXAMINER